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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,730	01/02/2002	Robert M. Abrams	269/106 (cont.)	3733

7590 10/18/2005

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EXAMINER	
SCHNIZER, RICHARD A	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,730	ABRAMS ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-41,43,44,46,53-57 and 59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-41,43,44,46,53-57 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/19/05 has been entered.

Claims 32-41, 43, 44, 46, 53-57, and 59 are pending.

In the response to restriction requirement filed 4/12/04 Applicant elected group 1 drawn to a precursor composition comprising polymer forming biodegradable material and a biologically active component wherein the biologically active component is a protein or peptide, classified in class 514, subclass 2. Applicant also elected the species of polyglycolic acid for claim 35 and the species polyhydroxybutyrate for claim 36.

Claims 32-41, 43, 44, 46, 53-57, and 59 are under consideration to the extent that they read on the elected invention.

Drawings

No drawings were filed with the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claims 32-41, 43, 44, 46, 53-57, and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims as amended embrace a system which includes a vaso-occlusive precursor which comprises a polymer-forming or dissolved polymeric biodegradable material in an amount of about 5 to 50% by weight. The claims do not specify what is to be taken into account when calculating the percent weight of the vaso-occlusive precursor. So, the claims continue to embrace an embodiment in which the weight of the entire "system", including the mechanical occlusive device of item c), is taken into account. As discussed in the previous Action, this is new matter. The specification provides no written support for a system comprising a mechanical occlusive device wherein a polymer-forming, or dissolved polymeric, biodegradable material constitutes 5-50% of the weight of **the entire system including the mechanical occlusive device**. Instead the specification supports polymer solutions of 5-50% (w/w) (see page 12, lines 5-15) that may be combined with a mechanical occlusive device. Neither the specification nor claims as filed supports the instant claim amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32, 33, 38, 39, 53-55, and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by Evans (US Patent 5,702,361).

Evans taught a system comprising embolizing polymer solutions in a biocompatible solvent and a non-particulate agent such as a metal coil. Preferred biocompatible polymers include cellulose diacetate and ethylene vinyl alcohol copolymer. In a preferred embodiment, the number average molecular weight, as determined by gel permeation chromatography, of the cellulose diacetate composition is from about 25,000 to about 100,000 more preferably from about 50,000 to about 75,000 and still more preferably from about 58,000 to 64,000. See column 5, lines 40-48. Preferably, the polymer composition will comprise from about 2.5 to about 8.0 weight percent of the biocompatible polymer composition based on the total weight of the polymer composition. See column 7, lines 10-18. Both components of the system are considered to be biologically active inasmuch as they cause clot formation. See e.g. column 9, lines 27-33. The particular biocompatible polymer employed is not critical and is selected relative to the viscosity of the resulting polymer solution, the solubility of

the biocompatible polymer in the biocompatible solvent, the compatibility of the polymer composition with the non-particulate agent and the like. Such factors are well within the skill of the art. See column 5, lines 34-39. The biocompatible solvent can be an aqueous mixture comprising ethanol. See column 6, lines 44-52.

Evans also taught a method in which the non-particulate agent (e.g., platinum coils) is first introduced to the vascular site to be embolized via conventional catheter technology. After introduction of the non-particulate agent to the vascular site, a sufficient amount of the polymer composition is introduced by conventional means (e.g., catheter delivery under fluoroscopy). See column 8, lines 12-23.

Evans also taught kits comprising:

(a) a polymer composition comprising a biocompatible polymer, a biocompatible solvent and a contrast agent; and

(b) a non-particulate agent or plurality of such agents; or

(a) a prepolymer composition comprising a biocompatible prepolymer and a contrast agent; and

(b) a non-particulate agent or plurality of such agents.

Preferably, in either case, the kit further comprises a catheter capable of delivering said polymer or prepolymer composition.

Thus Evans anticipates the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (US Patent 5,702,361) in view of Slepian (US Patent 5,634,946).

Evans taught a system comprising embolizing polymer solutions in a biocompatible solvent and a non-particulate agent such as a metal coil. Preferred biocompatible polymers include cellulose diacetate and ethylene vinyl alcohol copolymer. In a preferred embodiment, the number average molecular weight, as determined by gel permeation chromatography, of the cellulose diacetate composition is from about 25,000 to about 100,000 more preferably from about 50,000 to about 75,000 and still more preferably from about 58,000 to 64,000. See column 5, lines 40-48. Preferably, the polymer composition will comprise from about 2.5 to about 8.0 weight percent of the biocompatible polymer composition based on the total weight of the polymer composition. See column 7, lines 10-18. The particular biocompatible polymer employed is not critical and is selected relative to the viscosity of the resulting polymer solution, the solubility of the biocompatible polymer in the biocompatible solvent, the compatibility of the polymer composition with the non-particulate agent and the like. Such factors are well within the skill of the art. See column 5, lines 34-39.

Evans did not teach the use of polyesters or polyhydroxybutyrate as a biocompatible polymer.

Slepian taught a method for forming a biocompatible polymer coating on a tissue surface of a lumen in a body vessel, wherein the polymer is a biocompatible polymer selected from the group consisting of polymers and copolymers of hydroxycarboxylic acids, polyurethanes, polyesters, polyamides, polyacrylonitriles, polyphosphazenes, polylactones, polyanhydrides, polyethylenes, polyalkysulfones, polycarbonates, polyhydroxybutyrates, polyhydroxyvalerates, hydrocarbon polymers, polypropylenes polyvinylchlorides, ethylene vinyl acetates and combinations thereof. See claim 5. Slepian also taught that the polymers could be used to occlude a tissue lumen completely. See paragraph bridging columns 8 and 9.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use any of the polymers of Slepian in the method of Evans because these are considered to be recognized equivalents in the art of tissue lumen occlusion, and the invention of Evans is directed to occlusion of the lumens of blood vessels. MPEP 2144.06 indicates that when it is recognized in the art that elements of an invention can be substituted, one for the other, while retaining essential function, such elements are art-recognized equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Furthermore, MPEP 2144.07 indicates that the selection of a known material based on its suitability for its intended

use supports the determination of prima facie obviousness. See also Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945).

Thus the invention as a whole was prima facie obvious.

Claims 32, 40, 41, 43, 44, and 46, are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (US Patent 5,702,361) in view of Murayama et al (US Patent 5,891,192).

Evans taught a system comprising embolizing polymer solutions in a biocompatible solvent and a non-particulate agent such as a metal coil. Preferred biocompatible polymers include cellulose diacetate and ethylene vinyl alcohol copolymer. In a preferred embodiment, the number average molecular weight, as determined by gel permeation chromatography, of the cellulose diacetate composition is from about 25,000 to about 100,000 more preferably from about 50,000 to about 75,000 and still more preferably from about 58,000 to 64,000. See column 5, lines 40-48. Preferably, the polymer composition will comprise from about 2.5 to about 8.0 weight percent of the biocompatible polymer composition based on the total weight of the polymer composition. See column 7, lines 10-18.

Evans did not teach a biologically active component that is a protein or peptide.

Murayama taught that coating intralumenal coils led to improved performance by controlling thrombosis and increasing re-endothelialization and cell adhesion. See e.g. column 1, lines 57-67; column 2, line 64 to column 3, line 8; and paragraph bridging columns 5 and 6.

It would have been obvious to one of ordinary skill in the art to coat the coils of Evans with fibronectin, as taught by Murayama in order to obtain the improved performance taught by Murayama.

Thus the invention as a whole was prima facie obvious.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Richard Schnizer, Ph.D.